



# California Medical Device Recall Information



## Recall Name

### Fresenius Recalls NaturaLyte® Liquid Bicarbonate Concentrate Due to Bacterial Contamination

Recall Date	Product Description	Recalling Firm	Recall Reason
Initial: 04/04/14 (49 lots)  Expanded: 05/01/14 (9 lots)	<b>NaturaLyte®</b> Liquid Bicarbonate Concentrate, 6.4 liters  (Intended for use in hemodialysis machines)	<b>Fresenius Medical Care North America</b> Waltham, MA	<i>Potential for the product to develop higher bacteria levels during its shelf life than allowed by the company's internal specification.</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	Part Number: <b>08-4000-LB</b>  <a href="#">Affected Lot Numbers</a>	<b>CA</b> , nationwide	Manufactured:  August 2013 to April 2014  Distributed:  August 15, 2013 to April 7, 2014

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm399124.htm>